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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,277	11/28/2000	Oivin M. Guicherit	CIBT-P04-072	7556

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BOSTON, MA 02110-2624

EXAMINER

RAO, DEEPAK R

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/24/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/724,277

Applicant(s)
Guicherit et al.

Examiner
Deepak Rao

Art Unit
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 24, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 ☒ are pending in the application.
- 4a) Of the above, claim(s) 41-43 ☒ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-40 ☒ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1-43 are pending in this application.

Election/Restriction

Applicant's election with traverse of Group I in Paper No. 12 is acknowledged. The traversal is on the ground(s) that the restriction between Groups I-III is improper because there is no burdensome search involved. Upon reconsideration, the restriction between Groups I, II and III is withdrawn and Groups II and III are rejoined with Group I and examined together. Applicant did not provide any argument with respect to the remaining groups IV-VI, which restriction is hereby maintained.

Claims 41-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds of formula II, does not reasonably provide enablement for

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all other compounds embraced by the instant claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The specification fails to enable the preparation of the compounds that are used in the instantly claimed inhibitory method. The specification provides synthetic scheme in pages 86-89 to show the synthesis of compounds of formula II. However, the instant recitation of “a compound” in the claims reads on any and all compounds that are known. Further, among the exemplary compounds, the compounds represented by formula I reduce to H₂ (when the various substituents are either absent or direct bonds). There is no description regarding what type of compounds other than the quinazoline compounds disclosed in the Figure 32, that are intended to be useful in the invention. The exemplified compounds are structurally very different from other compounds embraced by the instant claims such that no reasonable extrapolation could be made by one skilled in the art to prepare all of the compounds commensurate in scope with the claims.

The specification fails to enable one skilled in the art to use the claimed invention. The use disclosed in the specification is use of the compounds of formula II as *hedgehog* antagonists

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useful in the treatment of variety of therapeutic and cosmetic applications. Assay to test/screen compounds for the activity and the results are disclosed at pages 90-95, however, all of the tested compounds are drawn to quinazolinone derivatives. The compounds for which test results are provided are structurally so dissimilar from the remaining compounds included in the claims such that no reasonable extrapolation could be made by one skilled in the art regarding the activity of the compounds. Further, applicants have not provided how the *in vitro* data provided for the compounds correlates to in vivo applications. Such correlation is necessary in receptor interactions which are highly structure specific and unpredictable. See Bale et al. (Human Molecular Genetics, 2001), in their publication regarding *hedgehog* pathway remarked that "The extensive phenotype variability does not correlate with the nature or location of mutations in *patched*" (see page 759, col. 2).

In view of the lack of direction provided in the specification regarding the starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. In claim 12, it is not understood with what type of 'normal cell' is subject to the inhibition by compound, i.e., is the 'cell' part of a muscle tissue in the body of a mammal? The claim does not clearly set forth what type of method is intended in the instant claim, e.g., a therapeutic method. Appropriate clarification or correction is required.
2. The recitation of claim 30 are confusing and unclear. It is not clear whether the structural formula depicted in the claim is the compound that is used in the therapeutic method or it is the compound which is excluded from the method.

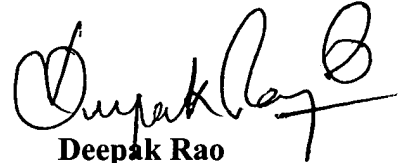
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (703) 305-1879. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (703) 308-4716. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Deepak Rao', with a stylized flourish at the end.

Deepak Rao
Primary Examiner
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September 23, 2003